Department of Health and Mental Hygiene

Larry J. Hogan, Jr. Governor - Boyd K. Rutherford, Lt. Governor - Van T. Mitchell, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue Baltimore, Maryland 21215-2299 Mitra Gavgani, Board President – Deena Speights-Napata, Executive Director

VIA REGULAR & CERTIFIED MAIL, RETURN RECEIPT REQUESTED ARTICLE #7014 2870 0000 4732 1523

December 2, 2016

UPM Pharmaceuticals, Inc. 501 5th Street Bristol, TN 37620 Attn: R. Gary Hollenbeck

Re:

Permit No. D03240 Case No. PI-17-030

Notice of Deficiencies, Recommended Civil Monetary Penalty, and

Opportunity for Hearing

Dear Mr. Hollenbeck:

On August 4, 2016, the Maryland Board of Pharmacy (the "Board") attempted to conduct an inspection of UPM, Inc. (the "Distributor") at 6200 Seaforth Street, Baltimore, MD, to determine if the Distributor was in compliance with State laws regarding the operation of a wholesale drug distributor. The inspector indicated that the Distributor was no longer operating at the above address of record and had relocated to Tennessee. The Board was not given notice that the Distributor ceased operations in Maryland in accordance with COMAR 10.34.22.10.

I. FINDINGS AND CONCLUSION

The Board finds that the Distributor failed to: (1) provide to the Board notice that it ceased operations in Maryland; and (2) submit to a closing inspection of the Maryland facility.

Based upon above deficiencies, the Board concludes that the Distributor is in violation of the Maryland Pharmacy Act and the regulations adopted thereunder. Specifically, the Board finds the Distributor in violation of Health Occ. Art. § 12-601, § 12-

II. RECOMMENDED CIVIL MONETARY PENALTY

Under Maryland Health Occupations Article § 12-6C-11 and COMAR 10.34.11, the Board of Pharmacy has the authority to impose a civil fine not to exceed \$500,000 based upon violations of the Maryland Pharmacy Act.

Based upon the deficiencies cited at the Distributor, the Board hereby recommends the imposition of a **civil fine of \$1,000.00**. The deficiencies upon which the civil fine is based are referenced above.

In determining the recommended civil monetary penalty, the Board took into consideration the aggregating and mitigating factors outlined in COMAR 10.34.11.08.

III. FOLLOW-UP ACTION

Please be advised that the Distributor shall submit a new wholesale distributor application to the Board in the event that the Distributor wishes to continue distributing prescription drugs or devices into Maryland from its Tennessee facility in accordance with COMAR 10.34.22.11. Unless otherwise authorized, the Distributor may not distribute prescription drugs or devices into Maryland from the Tennessee facility unless and until it receives a permit from Maryland for that facility. Health Occ. § 12-6C-04(g)

IV. OPPORTUNITY FOR HEARING

If the Distributor disputes the findings, conclusions or the civil monetary penalty, the Distributor may request an evidentiary hearing on the Board's decision in this matter. In the event that the Distributor requests an evidentiary hearing, the Board shall initiate formal proceedings which will include the opportunity for a full evidentiary hearing. The hearing will be held in accordance with the Administrative Procedure Act, Md. Code Ann. State Gov't § 10-201 et seq., and COMAR 10.34.01. Any request for a hearing must by submitted in writing to Vanessa Thomas Gray, Compliance Investigator, Maryland Board of Pharmacy, 4201 Patterson Ave., 5th Floor, Baltimore, Maryland 21215, no later than thirty (30) days of the date of this Notice.

Please be advised that at the hearing the Distributor has the following rights: to be represented by counsel, to subpoena witnesses, to call witnesses on your own behalf, to present evidence, to cross-examine witnesses, to testify, and to present summation and argument. Should the Board find the Distributor guilty of the violations cited in the Reports, the Board may reprimand, suspend or revoke the distributor permit, place the permit on probation, or impose a civil fine. If the Distributor requests a hearing but fails to appear,

the Board may nevertheless hear and determine the matter in the Distributor's absence.

V. OPTION TO PAY RECOMMENDED CIVIL MONETARY PENALTY

Alternatively, the Distributor may pay the recommended civil monetary penalty within thirty (30) days of the date of this Notice, in the form of a certified check or money order made payable to the Maryland Board of Pharmacy.

Please mail the check or money order to:

Maryland Board of Pharmacy P.O. Box 2051 Baltimore, MD 21203-2051

NOTE: Please include the case number, Pl-17-030, on your check or money order to insure proper assignment to your case.

Upon the Distributor's payment of the civil monetary penalty, this Notice will constitute the Board's final action with respect to the deficiencies cited herein and shall be a public document in accordance with the Maryland Public Information Act.

If you have any questions concerning the instructions contained in this letter, please contact Vanessa Thomas Gray, Compliance Investigator, at 410-764-2493.

Sincerely,

Deena Speights-Napata

Executive Director

cc: Linda M. Bethman, Board Counsel